UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

SANOFI-AVENTIS and SANOFI-AVENTIS U.S. LLC, Plaintiffs, v. ACTAVIS SOUTH ATLANTIC LLC, AUROBINDO PHARMA LTD., AUROBINDO PHARMA USA INC., MYLAN PHARMACEUTICALS INC., PAR PHARMACEUTICAL, INC., RANBAXY INC., RANBAXY LABORATORIES LIMITED, SUN PHARMACEUTICAL INDUSTRIES, INC., SUN PHARMACEUTICAL INDUSTRIES LTD, TEVA PHARMACEUTICALS USA, INC., TORRENT PHARMA INC. and TORRENT PHARMACEUTICALS LIMITED, Defendants.	:	CIVIL ACTION NO. 07-572 GMS

ANSWER, AFFIRMATIVE DEFENSES, COUNTERCLAIMS AND JURY DEMAND OF DEFENDANT AUROBINDO PHARMA USA INC. TO PLAINTIFFS' COMPLAINT

Defendant Aurobindo Pharma USA Inc. (referred to herein as "Aurobindo USA," and referred to in Plaintiffs' Complaint as "Aurobindo Inc."), by and through the undersigned attorneys, answers the Complaint of Plaintiffs Sanofi-Aventis and Sanofi-Aventis U.S. LLC ("Sanofi-Aventis US") as follows:

PARTIES

COMPLAINT:

1. Plaintiff sanofi-aventis is a corporation organized and existing under the laws of France, having its principal place of business at 174 avenue de France, Paris, France 75013.

ANSWER: Aurobindo USA lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 1, and therefore denies all such allegations.

COMPLAINT:

2. Plaintiff sanofi-aventis U.S. is a limited liability company organized and existing under the laws of Delaware with its North American headquarters located at 55 Corporate Drive, Bridgewater, New Jersey 08807.

ANSWER: Aurobindo USA lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 2, and therefore denies all such allegations.

COMPLAINT:

3. Upon information and belief, Defendant Actavis is a Delaware limited liability company having a place of business at 13800 NW 2nd Street, Ste-190, Fort Lauderdale, Florida 33325.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

4. Upon information and belief, Defendant Aurobindo Inc. is a Delaware corporation, and the wholly-owned subsidiary and agent of Defendant Aurobindo Ltd., having a place of business at 2400 Route 130 North, Dayton, New Jersey 08810.

ANSWER: Admitted.

COMPLAINT:

5. Upon information and belief, Defendant Aurobindo Ltd. is an Indian corporation having a place of business at Plot No. 2, Maitri Vihar, Ameerpet, Hyderabad – 500 038, Andhra Pradesh, India. Upon information and belief, Defendant Aurobindo Ltd. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district, through its wholly-owned subsidiary and agent Aurobindo Inc.

ANSWER: Aurobindo USA admits that Aurobindo Ltd. it is an Indian corporation having a place of business at Plot No. 2, Maitri Vihar, Ameerpet, Hyderabad – 500 038, Andhra Pradesh, India. Aurobindo USA denies the remaining allegations in Paragraph 5.

COMPLAINT:

6. Upon information and belief, Defendant Mylan is a West Virginia corporation having a place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia, 26504. Upon information and belief, Defendant Mylan manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

7. Upon information and belief, Defendant Par is a Delaware corporation having a place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

8. Upon information and belief, Defendant Ranbaxy Inc. is a Delaware corporation, and the wholly-owned subsidiary and agent of Defendant Ranbaxy Ltd., having a place of business at 600 College Road East, Princeton, New Jersey 08540.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

9. Upon information and belief, Defendant Ranbaxy Ltd. is an Indian corporation having a place of business at Plot 90, Sector 32, Gurgaon -122001 (Haryana), India. Upon

information and belief, Defendant Ranbaxy Ltd. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district, through its wholly-owned subsidiary and agent Defendant Ranbaxy Inc.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

10. Upon information and belief, Defendant Sun Inc. was a Michigan corporation, and the wholly-owned subsidiary and agent of Defendant Sun Ltd., having a place of business at 29714 Orion CT, Fannington Hills, Michigan 48334 at the time it submitted its Abbreviated New Drug Application. Upon information and belief, Sun Inc. dissolved as a corporation on or about July 15, 2007. Upon information and belief, Defendant Sun Inc. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

11. Upon information and belief, Defendant Sun Ltd. is an Indian corporation having a place of business at Acme Plaza, Andheri - Kurla Rd, Andheri (E), Mumbai - 400 059. Upon information and belief, Defendant Sun Ltd., itself and through its wholly-owned subsidiary and agent Defendant Sun Inc., manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

12. Upon information and belief, Defendant Teva is a Delaware corporation having a place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

13. Upon information and belief, Defendant Torrent Inc. is a Delaware corporation, and the wholly-owned subsidiary and agent of Defendant Torrent Ltd., having a place of business at 3585 Bellflower Drive, Portage, Michigan 49024.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

14. Upon information and belief, Defendant Torrent Ltd. is an Indian company having a place of business at Torrent House, Off Ashram Road, Ahmedabad - 380 009, Gujarat, India. Upon information and belief, Defendant Torrent Ltd. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district, through its wholly-owned subsidiary and agent Defendant Torrent Inc.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

NATURE OF THE ACTION

COMPLAINT:

15. This is a civil action for the infringement of United States Patent No. 4,661,491 ("the '491 patent") (Exhibit A) and United States Patent No. 6,149,940 ("the '940 patent") (Exhibit B). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*.

ANSWER: This Paragraph contains legal conclusions to which no answer is required. To the extent that an answer is required, Aurobindo USA admits that Plaintiffs' Complaint asserts a claim that purports to arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et*

seq., for infringement of U.S. Patent No. 4,661,491 and U.S. Patent No. 6,149,940 (collectively, "the patents-in-suit"). Aurobindo USA denies the remaining allegations of Paragraph 15.

JURISDICTION AND VENUE

COMPLAINT:

16. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Paragraph 16 contains legal conclusions to which no answer is required. To the extent an answer is required, Aurobindo USA admits that subject matter jurisdiction over Plaintiffs' infringement claim on the patents-in-suit is proper for claims directed to Aurobindo Ltd. and denies that subject matter jurisdiction exists over Plaintiffs' infringement claim on the patents-in-suit directed to Aurobindo USA. Aurobindo USA denies the remaining allegations of Paragraph 16.

COMPLAINT:

17. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to a Delaware company, Plaintiff sanofi-aventis U.S. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

ANSWER: Paragraph 17 contains legal conclusions to which no answer is required. To the extent that these allegations are directed towards a Defendant other than Aurobindo USA and an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph. As to Aurobindo USA, to the extent an answer is required, Aurobindo USA denies the factual allegations in Paragraph 17. Aurobindo USA denies the remaining allegations of this Paragraph.

COMPLAINT:

18. This Court has personal jurisdiction over Defendant Actavis by virtue of the fact that, *inter alia*, Actavis is a Delaware limited liability company.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

19. This Court has personal jurisdiction over Defendant Aurobindo Inc. by virtue of the fact that, *inter alia*, Aurobindo Inc. is a Delaware corporation.

ANSWER: Paragraph 19 contains legal conclusions to which no answer is required. To the extent an answer is required, Aurobindo USA admits that it is a Delaware corporation, but denies all remaining allegations of Paragraph 19.

COMPLAINT:

20. This Court has personal jurisdiction over Defendant Aurobindo Ltd. by virtue of, *inter alia*: (1) its presence in Delaware through its subsidiary and agent Aurobindo Inc.; and (2) its systematic and continuous contacts with Delaware, including through its subsidiary and agent Aurobindo Inc.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

21. This Court has personal jurisdiction over Defendant Mylan by virtue of, *inter alia*, its systematic and continuous contacts with Delaware.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

22. This Court has personal jurisdiction over Defendant Par by virtue of the fact that, *inter alia*, Par is a Delaware corporation.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

23. This Court has personal jurisdiction over Defendant Ranbaxy Inc. by virtue of the fact that, *inter alia*, Ranbaxy Inc. is a Delaware corporation.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

24. This Court has personal jurisdiction over Defendant Ranbaxy Ltd. by virtue of, *inter alia*: (1) its presence in Delaware through its subsidiary and agent Ranbaxy Inc.; and (2) its systematic and continuous contacts with Delaware, including through its subsidiary and agent Ranbaxy Inc.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

25. This Court has personal jurisdiction over Defendant Sun Inc. by virtue of, *inter alia*, its systematic and continuous contacts with Delaware.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

26. This Court has personal jurisdiction over Defendant Sun Ltd. by virtue of, *inter alia*, its systematic and continuous contacts with Delaware, including through its subsidiary and agent Sun Inc.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

27. This Court has personal jurisdiction over Defendant Teva by virtue of the fact that, *inter alia*, Teva is a Delaware corporation.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

28. This Court has personal jurisdiction over Defendant Torrent Inc. by virtue of the fact that, *inter alia*, Torrent Inc. is a Delaware corporation.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

29. This Court has personal jurisdiction over Defendant Torrent Ltd. by virtue of, *inter alia*: (1) its presence in Delaware through its subsidiary and agent Torrent Inc.; and (2) its systematic and continuous contacts with Delaware, including through its subsidiary and agent Torrent Inc.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

30. Venue is proper in this judicial district as to each defendant pursuant to 28 U.S.C. §§ 1391 and 1400(b).

ANSWER: Paragraph 30 contains legal conclusions to which no answer is required. To the extent that these allegations are directed towards a Defendant other than Aurobindo USA and an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph. As to Aurobindo USA, to conserve the resources of the parties and for purposes of judicial efficiency, Aurobindo USA will not contest venue in this judicial district for purposes of this multi-defendant action only. Aurobindo USA denies the remaining allegations of this Paragraph.

THE PATENTS

COMPLAINT:

31. On April 28, 1987, the '491 patent, titled "Alfuzosine Compositions and Use," was duly and legally issued by the United States Patent and Trademark Office ("PTO"). Plaintiff sanofi-aventis is the current assignee of the '491 patent. Plaintiff sanofi-aventis U.S. holds New Drug Application ("NDA") No. 21-287 on Uroxatral® brand alfuzosin hydrochloride extended release tablets, and is the exclusive distributor of Uroxatral® in the United States. The '491 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for Uroxatral®.

ANSWER: Paragraph 31 contains legal conclusions to which no answer is required. To the extent an answer is required, Aurobindo USA admits the following: (1) according to the online records of the PTO, the '491 patent, entitled "Alfuzosine Compositions and Use," issued on April 28, 1987; (2) according to the electronic assignment records of the PTO, Sanofi-Aventis is identified as the current assignee of record of the '491 patent; (3) according to the electronic version of the U.S. Food and Drug Administration's ("FDA") Orange Book publication (current through October 2007), "SANOFI AVENTIS US" is identified as the applicant for approved NDA No. 21-287 for Uroxatral® (alfuzosin hydrochloride) Extended Release Tablets 10 mg; and

(4) according to the electronic version of the Orange Book, the '491 patent is listed for the drug Uroxatral®. Aurobindo USA denies all remaining allegations of Paragraph 31.

COMPLAINT:

32. On November 21, 2000, the '940 patent, titled "Tablet with Controlled Release of Alfuzosine Chlorhydrate," was duly and legally issued by the PTO. Plaintiff sanofi-aventis and Jagotec AG are the current assignees of the '940 patent. Plaintiff sanofi-aventis has an exclusive license to Jagotec AG's interests in the '940 patent. Pursuant to that license, sanofi-aventis has the right to unilaterally bring and proceed with this action in its own name. Jagotec has also consented to sanofi-aventis bringing this action. The '940 patent is listed in the Orange Book for Uroxatral®.

ANSWER: Paragraph 32 contains legal conclusions to which no answer is required. To the extent an answer is required, Aurobindo USA admits the following: (1) according to the online records of the PTO, the '940 patent, entitled "Tablet With Controlled Release of Alfuzosine Chlorhydrate," issued on November 21, 2000; (2) according to the electronic assignment records of the PTO, Sanofi-Aventis and Jagotec AG are identified as the current assignees of record of the '940 patent; and (3) according to the electronic version of the Orange Book, the '940 patent is listed for the drug Uroxatral®. Aurobindo USA denies all remaining allegations of Paragraph 32.

Acts Giving Rise to this Action
Count I - Infringement of the '491 Patent by Defendants Actavis and Par

COMPLAINT:

33. Upon information and belief, Actavis submitted Abbreviated New Drug Application ("ANDA") 79-055 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 79-055 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfzosin hydrochloride 10 mg tablet product prior to the expiration of the '491 patent.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

34. Actavis alleged in ANDA 79-055 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '491 patent are invalid. Plaintiffs received written notification of ANDA 79-055 on or about August 17, 2007.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

35. Actavis' submission of ANDA 79-055 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '491 patent under 35 U.S.C. § 271(e)(2)(A). Actavis' commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

36. Par is jointly and severally liable for Actavis' infringement of the '491 patent. Upon information and belief, Par participated in, contributed to, aided, abetted and/or induced Actavis' submission of ANDA 79-055 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

37. Par's participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-055 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '491 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, Par's commercial manufacture, use, offer for sale or sale of the proposed generic versions of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

38. This is an exceptional case under 35 U.S.C. § 285 because Actavis and Par were aware of the existence of the '491 patent at the time of the submission of ANDA 79-055 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '491 patent.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

39. Plaintiffs will be irreparably harmed by Defendant Actavis' and Defendant Par's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

Count II - Infringement of the '940 Patent by Defendants Actavis and Par

COMPLAINT:

40. ANDA 79-055 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '940 patent.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

41. Actavis has alleged in ANDA 79-055 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '940 patent are not infringed by the manufacture, use or sale of the proposed generic version of sanofi-aventis' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-055 on or about August 17, 2007.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

42. Actavis' submission of ANDA 79-055 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Actavis' commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '940 patent.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

43. Par is jointly and severally liable for Actavis' infringement of the '940 patent. Upon information and belief, Par participated in, contributed to, aided, abetted and/or induced Actavis' submission of ANDA 79-055 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

44. Par's participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-055 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Par's commercial manufacture, use, offer for sale or sale of its proposed generic versions of sanofi-aventis' Uroxatral® brand product would infringe the '940 patent.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

45. This is an exceptional case under 35 U.S.C. § 285 because Actavis and Par were aware of the existence of the '940 patent at the time of the submission of ANDA 79-055 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '940 patent.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

46. Plaintiffs will be irreparably harmed by Defendant Actavis' and Defendant Par's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

Count III - Infringement of the '491 Patent by Defendants Aurobindo Ltd. and Aurobindo Inc.

COMPLAINT:

47. Upon information and belief, Aurobindo Ltd., through its subsidiary and agent Aurobindo Inc., submitted ANDA 79-060 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 79-060 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '491 patent.

ANSWER: Paragraph 47 contains legal conclusions to which no answer is required. To the extent an answer is required, Aurobindo USA admits that Aurobindo Pharma Ltd. ("Aurobindo Ltd.") submitted ANDA No. 79-060 to FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), and that Aurobindo Ltd.'s ANDA No. 79-060 seeks FDA approval for alfuzosin hydrochloride extended release tablets, 10 mg, before the expiration of the '491 patent. Aurobindo USA denies the remaining allegations on Paragraph 47.

COMPLAINT:

48. Aurobindo Ltd. alleged in ANDA 79-060 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '491 patent are invalid or not infringed by the manufacture, use or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-060 on or about August 30, 2007.

ANSWER: Aurobindo USA admits that Aurobindo Ltd.'s ANDA No. 79-060 contains a so-called "Paragraph IV Certification" pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), stating that the '491 patent is invalid, unenforceable and/or will not be infringed by the manufacture, sale or use of the drug product for which Aurobindo Ltd. submitted its ANDA No. 79-060. Aurobindo USA admits that Sanofi-Aventis US received Aurobindo Ltd.'s notice under 21 U.S.C. § 355(j)(2)(B) on August 30, 2007. Aurobindo USA denies all remaining allegations of Paragraph 48.

COMPLAINT:

49. Aurobindo Ltd.'s submission of ANDA 79-060 to the FDA, through Aurobindo Inc., including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '491 patent under 35 U.S.C. § 271(e)(2)(A). Aurobindo Ltd.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

ANSWER: Denied.

COMPLAINT:

50. Aurobindo Inc. is jointly and severally liable for Aurobindo Ltd.'s infringement of the '491 patent. Upon information and belief, Aurobindo Inc. participated in, contributed to, aided, abetted and/or induced Aurobindo Ltd.'s submission of ANDA 79-060 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

ANSWER: Denied.

COMPLAINT:

51. Aurobindo Inc.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-060 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '491 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, Aurobindo Inc.'s commercial manufacture, use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

ANSWER: Denied.

COMPLAINT:

52. This is an exceptional case under 35 U.S.C. § 285 because Aurobindo Ltd. and Aurobindo Inc. were aware of the existence of the '491 patent at the time of the submission of ANDA 79-060 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '491 patent.

ANSWER: Denied.

COMPLAINT:

53. Plaintiffs will be irreparably harmed by Defendant Aurobindo Ltd.'s and Defendant Aurobindo Inc.'s infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

ANSWER: Denied.

Count IV - Infringement of the '940 Patent by Defendants Aurobindo Ltd. and Aurobindo Inc.

COMPLAINT:

54. ANDA 79-060 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '940 patent.

ANSWER: Paragraph 54 contains legal conclusions to which no answer is required. To the extent an answer is required, Aurobindo USA admits that Aurobindo Ltd.'s ANDA No. 79-060 seeks FDA approval for alfuzosin hydrochloride extended release tablets, 10 mg, before the expiration of the '940 patent. Aurobindo USA denies all remaining allegations of Paragraph 54.

COMPLAINT:

55. Aurobindo Ltd. alleged in ANDA 79-060 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '940 patent are invalid or not infringed by the manufacture, use or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-060 on or about August 30, 2007.

ANSWER: Aurobindo USA admits that Aurobindo Ltd.'s ANDA No. 79-060 contains a so-called "Paragraph IV Certification" pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), stating that the '940 patent is invalid, unenforceable and/or will not be infringed by the manufacture, sale or use of the drug product for which Aurobindo Ltd. submitted its ANDA No. 79-060. Aurobindo USA admits that Sanofi-Aventis US received Aurobindo Ltd.'s notice under 21 U.S.C. § 355(j)(2)(B) on August 30, 2007. Aurobindo USA denies all remaining allegations of Paragraph 55.

COMPLAINT:

56. Aurobindo Ltd.'s submission of ANDA 79-060 to the FDA, through Aurobindo Inc., including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Aurobindo Ltd.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '940 patent.

ANSWER: Denied.

COMPLAINT:

57. Aurobindo Inc. is jointly and severally liable for Aurobindo Ltd.'s infingement of the '940 patent. Upon information and belief, Aurobindo Inc. participated in, contributed to, aided, abetted and/or induced Aurobindo Ltd.'s submission of ANDA 79-060 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

ANSWER: Denied.

COMPLAINT:

58. Aurobindo Inc.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-060 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, Aurobindo Inc.'s commercial manufacture, use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '940 patent.

ANSWER: Denied.

COMPLAINT:

59. This is an exceptional case under 35 U.S.C. § 285 because Aurobindo Ltd. and Aurobindo Inc. were aware of the existence of the '940 patent at the time of the submission of ANDA 79-060 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '940 patent.

ANSWER: Denied.

COMPLAINT:

60. Plaintiffs will be irreparably harmed by Defendant Aurobindo Ltd.'s and Defendant Aurobindo Inc.'s infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

ANSWER: Denied.

Count V - Infringement of the '491 Patent by Defendant Mylan

COMPLAINT:

61. Upon information and belief, Mylan submitted ANDA 79-014 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 79-014

specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '491 patent.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

62. Mylan alleged in ANDA 79-014 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '491 patent are invalid. Plaintiffs received written notification of ANDA 79-014 on or about August 27, 2007.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

63. Mylan's submission of ANDA 79-014 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '491 patent under 35 U.S.C. § 271(e)(2)(A). Mylan's commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

64. This is an exceptional case under 35 U.S.C. § 285 because Mylan was aware of the existence of the '491 patent at the time of the submission of ANDA 79-014 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '491 patent.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

65. Plaintiffs will be irreparably harmed by Defendant Mylan's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

Count VI – Infringement of the '940 Patent by Defendant Mylan

COMPLAINT:

66. ANDA 79-014 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '940 patent.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

67. Mylan alleged in ANDA 79-014 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '940 patent are not infringed by the manufacture, use or sale of the proposed generic version of sanofi-aventis' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-014 on or about August 27, 2007.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

68. Mylan's submission of ANDA 79-014 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Mylan has provided limited information related to its proposed generic version of sanofi-aventis' Uroxatral® brand product that is the subject of ANDA 79-014. However, given Mylan's claim of bioequivalence contained within ANDA 79-014, Plaintiffs believe that they are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery that will demonstrate that Mylan's commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand would infringe the '940 patent.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

69. This is an exceptional case under 35 U.S.C. § 285 because Mylan was aware of the existence of the '940 patent at the time of the submission of ANDA 79-014 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '940 patent.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

70. Plaintiffs will be irreparably harmed by Defendant Mylan's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

Count VII - Infringement of the '940 Patent by Defendants Ranbaxy Ltd. and Ranbaxy Inc.

COMPLAINT:

71. Upon information and belief, Ranbaxy Ltd., through its subsidiary and agent Ranbaxy Inc., submitted ANDA 79-006 to the FDA under §505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 79-006 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '940 patent.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

72. Ranbaxy Ltd. alleged in ANDA 79-006 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '940 patent are not infringed by the manufacture, use or sale of the proposed generic version of sanofi-aventis' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-006 on or about August 14, 2007.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

73. Ranbaxy Ltd.'s submission of ANDA 79-006 to the FDA, through Ranbaxy Inc., including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Ranbaxy Ltd.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand would infringe the '940 patent.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

74. Ranbaxy Inc. is jointly and severally liable for any infringement of the '940 patent. Upon information and belief, Ranbaxy Inc. participated in, contributed to, aided, abetted and/or induced Ranbaxy Ltd.'s submission of ANDA 79-006 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

75. Ranbaxy Inc.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-006 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '940 patent under 35 U.S.C. §271(e)(2)(A). Moreover, Ranbaxy lnc.'s commercial manufacture, use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '940 patent.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

76. This is an exceptional case under 35 U.S.C. § 285 because Ranbaxy Ltd. and Ranbaxy Inc. were aware of the existence of the '940 patent at the time of the submission of ANDA 79-006 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '940 patent.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

77. Plaintiffs will be irreparably harmed by Defendant Ranbaxy. Ltd.'s and Defendant Ranbaxy Inc.'s infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

Count VIII - Infringement of the '940 Patent by Defendants Sun Inc. and Sun Ltd.

COMPLAINT:

78. Upon information and belief, Sun Inc. acting as a subsidiary and agent of Sun Ltd., submitted ANDA 79-057 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA 79-057 seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 79-057 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '940 patent.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

79. Sun Inc. alleged in ANDA 79-057 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '940 patent are not infringed by the manufacture, use or sale of the proposed generic version of sanofi-aventis' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-057 on or about September 6, 2007.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

80. Sun Inc.'s submission of ANDA 79-057 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Sun Inc. has provided no information related to its proposed generic version of sanofi-aventis' Uroxatral® brand product that is the subject of ANDA 79-057. However, given Sun Inc.'s claim of bioequivalence contained within ANDA 79-057, Plaintiffs believe that they are likely to have evidentiay support after a reasonable opportunity for further investigation or

discovery that will demonstrate that Sun Inc.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand would infringe the '940 patent.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

81. Sun Ltd. is jointly and severally liable for Sun Inc.'s infringement of the '940 patent. Upon information and belief, Sun Ltd. participated in, contributed to, aided, abetted and/or induced Sun Inc.'s submission of ANDA 79-057 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

82. Sun Ltd.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-057 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Sun Ltd.'s commercial manufacture, use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '940 patent.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

83. This is an exceptional case under 35 U.S.C. § 285 because Sun Inc. and Sun Ltd. were aware of the existence of the '940 patent at the time of the submission of ANDA 79-057 and their § 505(j)(2)(A)(vii)(1V) allegations to the FDA and that filing constituted infringement of the '940 patent.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

84. Plaintiffs will be irreparably harmed by Defendant Sun Inc.'s and Defendant Sun Ltd.'s infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

Count IX - Infringement of the '491 Patent by Defendant Teva

COMPLAINT:

85. Upon information and belief, Teva submitted ANDA 79-056 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 79-056 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '491 patent.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

86. Teva alleged in ANDA 79-056 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '491 patent are invalid or not infringed by the manufacture, use or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-056 on or about August 15, 2007.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

87. Teva's submission of ANDA 79-056 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '491 patent under 35 U.S.C. § 271(e)(2)(A). Teva's commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

88. Thus is an exceptional case under 35 U.S.C. § 285 because Teva was aware of the existence of the '491 patent at the time of the submission of ANDA 79-056 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '491 patent.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

89. Plaintiffs will be irreparably harmed by Defendant Teva's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

Count X – Infringement of the '940 Patent by Defendant Teva

COMPLAINT:

90. ANDA 79-056 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '940 patent.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

91. Teva alleged in ANDA 79-056 under § 505(j)(2)(A)(vii)(IV) of the, Federal Food, Drug and Cosmetic Act that the claims of the '940 patent are not infringed by the manufacture, use or sale of the proposed generic version of sanofi-aventis' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-056 on or about August 15, 2007.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

92. Teva's submission of ANDA 79-056 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Teva has provided limited information related to its proposed generic version of sanofi-aventis' Uroxatral® brand product that is the subject of ANDA 79-056. However, given Teva's claim of bioequivalence contained within ANDA 79-056, Plaintiffs believe that they are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery that will demonstrate that Teva's commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand would infringe the '940 patent.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

93. This is an exceptional case under 35 U.S.C. § 285 because Teva was aware of the existence of the '940 patent at the time of the submission of ANDA 79-056 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '940 patent.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

94. Plaintiffs will be irreparably harmed by Defendant Teva's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

Count XI - Infringement of the '491 Patent by Defendants Torrent Ltd. and Torrent Inc.

COMPLAINT:

95. Upon information and belief, Torrent Ltd., through its subsidiary and agent Torrent Inc., submitted ANDA 79-054 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 79-054 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '491 patent.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

96. Torrent Ltd. alleged in ANDA 79-054 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '491 patent are invalid. Plaintiffs received written notification of ANDA 79-054 on or about August 16, 2007.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

97. Torrent Ltd.'s submission of ANDA 79-054 to the FDA, through Torrent Inc., including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '491 patent under 35 U.S.C. § 271(e)(2)(A). Torrent Ltd.'s commercial use, offer for sale or sale of its proposed generic version, of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

98. Torrent Inc. is jointly and severally liable for any infringement of the '491 patent. Upon information and belief, Torrent Inc. participated in, contributed to, aided, abetted and/or induced Torrent Ltd.'s submission of ANDA 79-054 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

99. Torrent Inc.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-054 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '491 patent under 35 U.S.C. § 271(e)(2)(A). Torrent Inc.'s commercial manufacture, use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

100. This is an exceptional case under 35 U.S.C. § 285 because Torrent Ltd. and Torrent Inc. were aware of the existence of the '491 patent at the time of the submission of ANDA 79-054 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '491 patent.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

101. Plaintiffs will be irreparably harmed by Defendant Torrent Ltd.'s and Defendant Torrent Inc.'s infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

Count XII - Infrinegement of the '940 Patent by Defendants Torrent Ltd. and Torrent Inc.

COMPLAINT:

102. ANDA 79-054 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '940 patent.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

103. Torrent Ltd. alleged in ANDA 79-054 Under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '940 patent are invalid and not infringed by the manufacture, use or sale of the proposed generic version of sanofi-aventis' Uroxatral® brand product. Plaintiffs received written notification of ANDA 79-054 on or about August 16, 2007.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

104. Torrent Ltd.'s submission of ANDA 79-054 to the FDA, through Torrent Inc., including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Torrent Ltd.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand would infringe the '940 patent.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

105. Torrent Inc. is jointly and severally liable for Torrent Ltd.'s infringement of the '940 patent. Upon information and belief, Torrent Inc. participated in, contributed to, aided, abetted and/or induced the submission of ANDA 79-054 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

106. Torrent Inc.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-054 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '940 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, Torrent

Inc.'s commercial manufacture, use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '940 patent.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

107. This is an exceptional case under 35 U.S.C. § 285 because Torrent Ltd. and Torrent Inc. were aware of the existence of the '940 patent at the time of the submission of ANDA 79-054 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '940 patent.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

COMPLAINT:

108. Plaintiffs will be irreparably harmed by Defendant Torrent Ltd.'s and Defendant Torrent Inc.'s infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

ANSWER: These allegations are directed towards a Defendant other than Aurobindo USA. To the extent an answer by Aurobindo USA is required, Aurobindo USA denies the allegations of this Paragraph.

Aurobindo USA denies all allegations not expressly admitted herein. Aurobindo USA further denies that Plaintiffs are entitled to any of the relief requested, and requests that Plaintiffs' complaint be dismissed with prejudice and that Aurobindo USA be awarded its fees and costs incurred defending this suit under 35 U.S.C. § 285.

DEFENSES

Without prejudice to the denials set forth in its Answer, without admitting allegations of the Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on Plaintiffs, Aurobindo USA asserts the following defenses to the Complaint:

First Defense

The claims of U.S. Patent No. 4,661,491 ("the '491 patent") are invalid under one or more provisions of 35 U.S.C. § 101 *et seq*.

Second Defense

The manufacture, use, sale, offer for sale, or importation of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Aurobindo Ltd.'s ANDA No. 79-060 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '491 patent.

Third Defense

The claims of U.S. Patent No. 6,149,940 ("the '940 patent") are invalid under one or more provisions of 35 U.S.C. § 101 *et seq*.

Fourth Defense

The manufacture, use, sale, offer for sale, or importation of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Aurobindo Ltd.'s ANDA No. 79-060 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '940 patent.

Fifth Defense

The Court lacks subject matter jurisdiction over patent infringement claims directed to Defendant Aurobindo USA.

Sixth Defense

Venue is not proper in this judicial district.

Seventh Defense

Any additional defenses or counterclaims that discovery may reveal, including, but not limited to, defenses of unenforceability, as well as any defense(s) raised by another defendant in this action.

COUNTERCLAIMS

Aurobindo Pharma USA Inc. ("Aurobindo USA"), for its Counterclaims against Sanofi-Aventis and Sanofi-Aventis U.S. LLC (collectively, "Plaintiffs"), alleges as follows:

The Parties

1. Aurobindo USA is a Delaware corporation, and the wholly-owned subsidiary and agent of Defendant Aurobindo Ltd., having a place of business at 2400 Route 130 North, Dayton, New Jersey 08810.

2. Aurobindo Ltd. is a corporation organized and existing under the laws of India, having a place of business at Plot No. 2, Maitri Vihar, Ameerpet, Hyderabad – 500 038, Andhra Pradesh, India.

3. Sanofi-Aventis purports to be a corporation organized and existing under the laws of France, having a principal place of business at 174 Avenue de France, Paris, France.

4. Sanofi-Aventis U.S. LLC ("Sanofi-Aventis US") purports to be a limited liability company formed under the laws of the State of Delaware, having commercial headquarters at 55 Corporate Drive, Bridgewater, New Jersey 08807.

Jurisdiction and Venue

5. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA") (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

6. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and under the MMA (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

7. This Court has personal jurisdiction over Plaintiffs because Plaintiffs have availed themselves of the rights and privileges of this forum by suing Aurobindo USA in this District, and because Plaintiffs conduct substantial business in, and have regular and systematic contacts with, this District.

8. Venue is proper in this District under 28 U.S.C. §§ 1391(b), (c) and 1400(b).

Patents-in-Suit

9. On or about April 28, 1987, the United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 4,661,491, entitled "ALFUZOSINE COMPOSITIONS AND USE," to François Regnier.

10. Plaintiff Sanofi-Aventis purports and claims to own, and to have the right to enforce, the '491 patent.

11. On or about November 21, 2000, the PTO issued U.S. Patent No. 6,149,940, entitled "TABLET WITH CONTROLLED RELEASE OF ALFUZOSINE CHLORHYDRATE," to Lauretta Maggi, Ubaldo Conte, Busto Arisizio, Pascal Grenier, Guy Vergnault, Alain Dufour, François Xavier Jarreau, and Clemence Rauch-Desanti.

12. Plaintiff Sanofi-Aventis purports and claims to own, and to have the right to enforce, the '940 patent.

13. On or about September 21, 2007, Plaintiffs sued Aurobindo Ltd. and Aurobindo USA in this District alleging infringement of the '491 patent and the '940 patent under 35 U.S.C. § 271(e)(2)(A).

14. Aurobindo Ltd. has submitted an abbreviated new drug application (ANDA) to FDA, which FDA assigned number 79-060. Aurobindo Ltd.'s ANDA seeks FDA approval for alfuzosin hydrochloride extended release tablets, 10 mg, before the expiration of the '491 patent and the '940 patent.

COUNT I
(Declaration of Non-Infringement of the '491 Patent)

15. Aurobindo USA realleges and incorporates by reference the allegations of Paragraphs 1-14.

16. A present, genuine, and justiciable controversy exists between Plaintiffs and Defendant Aurobindo USA regarding, *inter alia*, the infringement of any valid or enforceable claim of the '491 patent.

17. The manufacture, use, or sale of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Aurobindo's Ltd.'s ANDA No. 79-060 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '491 patent.

18. Aurobindo USA is entitled to a declaration that the manufacture, use, or sale of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Aurobindo Ltd.'s ANDA No. 79-060 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '491 patent.

COUNT II
(Declaration of Invalidity of the '491 Patent)

19. Aurobindo USA realleges and incorporates by reference the allegations of Paragraphs 1-18.

20. A present, genuine, and justiciable controversy exists between Plaintiffs and Defendant Aurobindo USA regarding, *inter alia*, the validity of the claims of the '491 patent.

21. The claims of the '491 patent are invalid under one or more provisions of 35 U.S.C. § 101 *et seq*.

22. Aurobindo USA is entitled to a declaration that the claims of the '491 patent are invalid.

COUNT III
(Declaration of Non-Infringement of the '940 Patent)

23. Aurobindo USA realleges and incorporates by reference the allegations of Paragraphs 1-22.

24. A present, genuine, and justiciable controversy exists between Plaintiffs and Defendant Aurobindo USA regarding, *inter alia*, the infringement of any valid or enforceable claim of the '940 patent.

25. The manufacture, use, or sale of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Aurobindo's Ltd.'s ANDA No. 79-060 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '940 patent.

26. Aurobindo USA is entitled to a declaration that the manufacture, use, or sale of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Aurobindo

Ltd.'s ANDA No. 79-060 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '940 patent.

COUNT IV
(Declaration of Invalidity of the '940 Patent)

27. Aurobindo USA realleges and incorporates by reference the allegations of Paragraphs 1-26.

28. A present, genuine, and justiciable controversy exists between Plaintiffs and Defendant Aurobindo USA regarding, *inter alia*, the validity of the claims of the '940 patent.

29. The claims of the '940 patent are invalid under one or more provisions of 35 U.S.C. § 101 *et seq*.

30. Aurobindo USA is entitled to a declaration that the claims of the '940 patent are invalid.

JURY DEMAND

Aurobindo USA demands a trial by jury.

REQUEST FOR RELIEF

WHEREFORE, Defendant Aurobindo Pharma USA Inc. respectfully requests that this Court enter a Judgment and Order in its favor and against Plaintiffs Sanofi-Aventis and Sanofi-Aventis US as follows:

(a) Declaring that the manufacture, use, or sale of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Aurobindo's Ltd.'s ANDA No. 79-060 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '491 patent;

(b) Declaring that the claims of the '491 patent are invalid;

(c) Declaring that the manufacture, use, or sale of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Aurobindo's Ltd.'s ANDA No. 79-060 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '940 patent;

(d) Declaring that the claims of the '940 patent are invalid;

(e) Declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Aurobindo USA its attorneys' fees, costs, and expenses in this action; and

(f) Awarding Aurobindo USA any further and additional relief as the Court deems just and proper.

Dated: November 5, 2007.

Respectfully submitted,

AUROBINDO PHARMA USA INC.

By: */s/ Mary B. Matterer*

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